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APPLICATION NUMBER	09/060,872	FILING DATE	04/15/98	FIRST NAMED APPLICANT	ESTELL	ATTY. DOCKET NO.	D 60527
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EXAMINER

SAUNDERS, D	
ART UNIT	PAPER NUMBER

1644

15

DATE MAILED: 01/12/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 9/29/99
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-16 is/are pending in the application.
- Of the above, claim(s) 1-12, 15-16 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 13-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 14
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Cancelled
The claims pending are 1-16. Claims 13-14 are under examination.

The amendment of 9/29/99 (Paper 13) has entered no new matter.

Amplified with
The requirement for applicant to comply with 37 CFR 1.821-1.825 remains. Applicant's response of Paper 13 has indicated that a sequence listing was filed concurrently. None can be found in this application. The concurrently filed "Request for use of an Identical..." (Paper 14) refers to a CRF filed in application 09/255,502. This request is confusing because it refers to this CRF as that of the "first-filed patent application". It is noted 09/255,502 was filed after the instant application. Also the "Request..." is in error by stating that "the Sequence listing was originally filed in the present patent application". None was filed originally or at any other time. Therefore no statement of identity can be properly made.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is confusing in relationship to amended base claim 13. The base claim was amended to require a modification in step b) that "induces less than a substantially equal" proliferation of T-cells relative to a baseline. Claim 14 recites, in steps b) and c), "a lesser allergic response from T-cells". Is this "allergic response" the same as, or something different from the "proliferation of T-cells" measured in base claim 13? If the former, then claim 14 is inconsistent with base claim 13, since "a lesser allergic response" (claim 14) is clearly of a scope *greater?* [^] than "less than or substantially equal the base line" (claim 13).

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The previously stated prior art rejection over King (5,593,877) has been withdrawn, since King does not teach modified peptides/proteins identified in terms of a proliferative response of the T-cells thereto.

Claims 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Garman et al (5,820,862).

This rejection is maintained for reasons of record and for reasons explained below, in light of applicant's urgings of Paper 13.

Applicant has urged that claims 13-14 require that the modified protein not be recognized --i.e. does not bind to a T-cell receptor that binds the non-modified epitope/protein. Applicant urges that page 5, line 30 supports. The examiner cannot find this teaching at page 5, line 30. In any event, this limitation is not a feature of the instant claims and, thus, will be given no weight.

Applicant has urged that Janeway defines T-cell anergy as requiring binding of peptides to T-cells without the context of class II MHC. The Janeway reference was not provided, and the examiner will give it no evidentiary weight since the term "anergy" merely means "impaired or absent ability to react to specific antigens" (Taber's cyclopedic medical Dictionary), and the definition given by Janeway (after the instant filing date) is merely one interpretation of the mechanism underlying anergy.

In any event, it can be seen that Garman et al define peptides that have been modified to induce anergy as those which "bind MHC proteins without the ability to induce a strong proliferative response, or possibly any proliferative response" (col.20, lines 27-30). This

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teaching is consistent with what applicant's claim language, in fact, is by way of the added limitation to claim 13, step b).

Applicant's urgings of Paper 13 are unconvincing because the arguments do not pertain to the limitations recited in the claims or to the explicit teaching of the reference.

Applicant has amended claim 13 to recite limitations regarding proliferation of T-cells to the modified protein in step (b). Since applicant may consider the quantitative relationships in this limitation to be of significance, the examiner is stating the following new ground of rejection.

Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fehlner et al (Jour. Immunol. 146, 799,1991).

Fehlner et al show identification of a T-cell epitope corresponding to residues 8-19 of melittin-- an allergen in bee venom. See paragraph spanning pages 801-802. This corresponds to instant step (a).

Fehlner et al then identify modified T-cell epitope peptides which do not induce proliferation of T-cells. See Figures 2 and 5. Note that peptides 7-21 (L12,Q14) and 7-21 (L12,K14) are inactive. See Figure 5 and paragraph spanning cols. 1-2 of page 803. The inactivity of these peptides in stimulating T-cell proliferation is consistent with the quantitative limitations now recited in claim 13, step (b). The substitutions in the peptide 7-21 (L12,K14) are considered consistent with the limitations of claim 14, part (c), since Figure 5 indicates that this peptide had essentially the same percent helical structure as the unmodified peptide 7-21.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

done
In any response applicant should cancel claims 1-12 and 15-16, non-elected without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 to 4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/sg

January 10, 2000

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/1044